UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.,* C. A. No. 06-11337-PBS	)	Hon. Patti Saris

MEMORANDUM BY THE UNITED STATES RELATING TO THE *IN CAMERA* SUBMISSION OF DOCUMENTS

The United States files this memorandum concurrently with its submission of documents for *in camera* review by the Court following the hearing on November 13, 2008. At that hearing, the Court directed the Government to consider whether it would continue to assert the deliberative process privilege with respect to certain documents withheld from production in these matters and to submit *in camera* documents for which it wished to maintain its privilege assertion. The Government has complied with that direction and has released documents from a very substantial portion of the entries on the schedule appended to defendants' special master motion. The Government submits this brief to describe the documents or categories of documents as to which the Government is maintaining its claim of privilege so as to expedite the Court's review of this material.

Background

1. The Parties' Document Productions and Privilege Logs

At this point in the MDL, the Government has been producing both documents and associated privilege logs for over three and a half years. The Government's document production began in July 2004 in response to subpoenas from the MDL defendants. On March 31, 2005, the Government issued a privilege log for documents withheld from that production. Over the course of the last several years, the Government has reviewed and refined the privilege assertions relating to the subpoenaed material. For example, in February 2007, the Government reviewed the privilege assertions made in the context of the MDL subpoena production, produced previously-withheld documents to defendants, and then issued a revised log.

In February 2007, the Government began a rolling production of documents in response to discovery requests by defendants in the cases where the Government had intervened and which had been transferred to the MDL. The Government made its final production to Abbott in April 2008, the close of fact discovery in the Abbott case. Consistent with the governing Case Management Order (CMO) provisions, the Government produced privilege logs in conjunction with its rolling production of documents.[1] The Government began issuing amended or supplemental logs in February 2007, and produced eight additional logs on a rolling basis over the ensuing thirteen months. The Government issued all its privilege logs before the close of fact discovery in the Abbott case.

While the Government was diligently working to comply with the CMO logging requirements, and although the production and logging requirements set forth in the CMOs apply

[1] Which generally require that logs issue within 30 days of production of the material from which the privileged documents were withheld.

equally to defendants and plaintiffs, they have been largely ignored by defendants. Although the deadline by which the Government had to complete its deposition discovery of Abbott witnesses was March 31, 2008, the bulk of Abbott's document production (*in excess of 2.2 million pages of material)* occurred *after* that date. On May 19, 2008, Abbott produced a privilege log *containing over 900 entries***.** Abbott produced its log *over six weeks after deposition discovery closed.*

On November 11, 2008, Abbott filed a brief asking the Court to appoint a special master to review the Governments' privilege assertions in this MDL. In support of that motion, Abbott, for the very first time, raised issues concerning certain entries on the Government's privilege logs. *See* Schedule 1 to Abbott's motion for a special master. Although Abbott previously raised the fundamental issue of whether the Government could assert the deliberative process privilege while a plaintiff in this action and had challenged the Government's privilege assertion for certain broad categories of documents, Abbott never sought to meet and confer with the Government concerning particular entries on a Government privilege log. Indeed, a very substantial portion of the entries on the schedule appended to defendants' special master motion were drawn from a privilege log issued by the Government in March 2005 relating to the Government's initial production of documents in the MDL. At no time over the past *three and a half years* has a defendant challenged any of the individual entries now before the Court, or even so much as attempted to confer with the Government regarding the particular documents covered by those log entries.

2. <u>The Nov. 13 Status Conference and the Government's Ensuing Document Production</u>

At the November 13, 2008 status hearing, the Court expressed its views with respect to general principles which the Government should consider when reviewing its privilege assertions

in these cases. Government counsel agreed to reassess the documents in light of the points stated by the Court. The Court directed the Government to submit, *in camera*, any documents described on the schedule appended to defendants' motion for which it would continue to assert the deliberative process privilege following its review. The schedule appended to defendants' motion for a special master lists 184 documents. Immediately following the November 13 hearing, Department of Justice counsel began conferring with agency counsel for Department of Health and Human Services' Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS). On November 21, 2008, the Government produced all documents covered by 94 entries on defendants' schedule and released portions of material covered by an additional 8 privilege log entries. The Government produced documents covered by an additional 12 entries on defendants' schedule on November 26, and released documents from another 4 entries on December 5. The Government will produce additional documents from the log this week.

At this point, there are 75 entries still at issue - although in many instances the Government released some material covered by an entry. As explained below, 38 of the documents now being submitted to the Court fall into a single discrete category (internal OIG memoranda recording certain conferences that occurred during audits and inspections). Additionally, material covered by defendants' schedule includes documents protected by the attorney-client privilege and work product doctrine – in other words, material that is not subject to release irrespective of the balancing test applied to documents protected by the deliberative process privilege.

Documents Submitted for *In Camera* Inspection

The documents being submitted to the Court fall into two main groups – 18 documents from the files of CMS, and 57 documents from the files of the OIG. The CMS documents are described in the declaration by Assistant Administrator Herbert Kuhn appended to this memorandum as Exhibit One and, in summary form, in this brief as well. The OIG documents fall principally into two subcategories. The first subcategory of OIG documents are from the workpapers associated with audits and inspections, and consist of notes and memoranda relating to entrance and exit conferences and team review meetings held during the audits and inspections, as well as draft versions of OIG reports. The second subcategory includes documents created outside the time frame at issue in this case[2] or drafts of documents, the final versions of which have been publicly released. The declaration by Assistant Inspector General Brian Ritchie, appended to this brief as Exhibit Two, discusses these documents and the OIG's interest in maintaining the confidentiality of the information contained therein.

Prior briefs by the Government relating to *in camera* submissions set out the principles controlling the deliberative process privilege, and are incorporated herein, by reference. *See, e.g.* Dkt. No. 5551.[3] *See also, Moye, O'Brien, O'Rourke, Hogan, & Pickert v. Nat'l R.R. Passenger*

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[2] The Court has stated that the Government will not be required to submit documents created after 2003 for *in camera* review, unless the documents refer back to policies or information from prior to 2004.

[3] Factors pertinent to whether deliberative material should be produced are:

> (i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

Corp., 376 F.3d 1270, 1279 (11th Cir. 2004*)* (explaining that "consultative and deliberative" material broadly includes ''recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency" (quoting *City of Virginia Beach, Virginia v. United States Dep't of Commerce,* 995 F.2d 1247, 1253 (4th Cir.1993)).

An application of these principles to the *in camera* submission by the Government weighs heavily in favor of nondisclosure with respect to the particular documents at issue.

A. CMS Documents

1. Internal CMS Deliberative Documents Relating to Agency Policies

Documents from this category are located at Tabs 1(A) through (L) in the *in camera* submission.

Tabs 1A and B These documents are draft versions of preamble language relating to Physician Fee Schedules from 1996 and 1998. *See* Kuhn Decl. ¶ 5. The documents contain hand-written marginalia with proposed edits. Final versions of the preambles were released in the Federal Register. The Court's November 5 decision regarding a prior *in camera* submission of documents by the Government noted that "marked up drafts are privileged." Dkt. 5665 at 18. The Court has also found that with respect to draft material, defendants' interests do not outweigh those of the Government when a final version of the document has been produced or is available. *Id*. at 19. Both principles operate here. The documents at issue set out draft language relating to federal regulations for which there are publicly available final versions.

In re Franklin Nat'l Bank Sec. Litig., 478 F. Supp 577, 583 (E.D.N.Y. 1979)

Tabs 1C and D The document at Tab 1C is from notes written by a CMS program analyst. The note discusses provisions which were deleted from a set of CMS final rules during deliberations relating to the rulemaking. Mr. Kuhn's declaration discusses his agency's interest in avoiding confusion about the actual final statements of agency policy. *See* Kuhn Decl. ¶ 8. Regulatory provisions which are dropped before issuance of a final rule and which were never publicly released are irrelevant. The document at Tab 1D is entitled "AWP Rule Payment Impact" and is dated July 25, 2003. The Notice of ProposedFinal Rulemaking to which the document relates was issued on August 20, 2003.

Tabs 1E through K The documents behind these tabs are options papers and proposals developed by CMS staff. *See* Kuhn Decl. ¶¶ 5a-5e.

The document at Tab 1E is entitled "Medicare AWP Drug Pricing." It discusses work by the Department of Justice (in and around 2000) developing information about actual transaction prices for drugs and sets out options and recommendations for certain issues associated with that price data. The document is, on its face, pre-decisional and related to the establishment of policy. The document is also irrelevant to any claim or defense in this case. The agency's official position on the use of the alternative AWP pricing information was explicitly set out in a publicly released Program Memorandum in 2000. *See* HCFA Prog. Mem. AB-00-86 (Sept. 8, 2000).

The document at Tab 1F is entitled "Pharmacy Team Collaboration with CMM [Center for Medicare Management] to Improve Drug Pricing Data" and has appended to it notes from a conference call within the agency and a call with OIG. The paper lays out options regarding the potential of using alternative data for determining payment amounts for drugs. The documents, on their face, discuss policy options and are prospective in nature. The document did not

establish policy for CMS. The document is not probative with respect to any claim or defense in this case.

The draft option and recommendation memorandum at Tab 1G is, on its face, clearly a pre-decisional, deliberative, non-final draft document containing handwritten marginalia. The document is not probative with respect to any claim or defense in this case.

The documents at Tab 1H are identical copies of an option and recommendation memorandum. As with prior documents, the document discusses the DOJ drug prices, lays out options regarding the use of those prices by Medicare Carriers, and concludes with a recommendation. The second copy of the document reflects concurrence in the recommendation by another CMS official. (*See* HHD924-0013). The document does not reflect the decision which resulted from the recommendation. The document is, on its face, pre-decisional and related to the establishment of policy. Ultimately, the agency's position on the use of the alternative AWP pricing information was explicitly set out in a publicly released Program Memorandum. *See* HCFA Prog. Mem. AB-00-86 (Sept. 8, 2000). The documents at Tab 1H are irrelevant to any claim or defense in this case.

The documents at Tab 1I all relate to a draft proposal to set payment amounts for drugs based on Relative Value Units ("RVUs") - i.e. the method used to establish payment amounts for other practice expenses covered by the Medicare Physician Fee Schedule. The documents discuss the "pros and cons" of such a methodology, and include draft material that could have been used to implement this methodology as well as documents containing comments from

agency staff on the draft proposal.[4] The material is wholly irrelevant. It relates to a hypothetical payment methodology that was never even formally proposed, much less implemented.

The documents at Tab 1J consist of a memorandum captioned "Alternative Payment Ideas for Currently Covered Medicare Drugs" and related notes and emails. It is clear from the face of the documents that they are deliberative in nature and concern potential payment methodologies that the agency might consider implementing. As such, they are core deliberative process material to which the privilege plainly applies. Again, the payment policies which the Government actually adopted are set out in official public documents. The documents behind Tab K are wholly irrelevant to any claim or defense in this case.

The material at Tab 1K is a briefing memorandum for the CMS Administrator relating to the Notice of Proposed Rulemaking ("NPRM") for the 1996 Physician Fee Schedule. The document, on its face, sets forth and discusses proposals relating to issues covered by the Fee Schedule regulation, including drug pricing. The Government's official and final policy regarding the subjects covered by this document is set out in the Notice of Final Rulemaking relating to the 1996 Physician Fee Schedules – a document that was publicly released in the Federal Register.

The documents behind Tab 1L are drafts of an "Initial Notice of Inherent Reasonableness" and related documents which include comments from agency and carrier

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[4] The material at Tab 1I appears to consist of multiple documents. In processing documents both for production and privilege logging, the Government has attempted to maintain the format of the original files. Because the documents at Tab I were submitted by agency staff as a discrete package of material, that organization was retained for the purposes of this *in camera* submission. This is also the case with respect to the material at Tabs 1J and L. It bears noting that the nature of any single document behind one of these tabs is more easily understood if the document is reviewed in context with the other documents in the package.

personnel.[5] The draft nature of the documents is clear from their face. The final version of the notice has been produced in this case. The draft versions are irrelevant.

2. Other Documents from CMS Files

The document behind Tab 2A is a draft memorandum from a Special Assistant to the President for Economic Policy bearing an October 2003 date. Because the document did not originate with CMS, it is not covered by Mr. Kuhn's declaration. The draft memorandum bears a "close hold" stamp. As of the date of this filing, undersigned Government counsel is attempting to confer with the White House regarding the status of the document. In the meantime, the Government submits that the Court should not order release of the document in light of its October 2003 date – which is just two months shy of the cut-off date stated by the Court at the November 13 hearing.

The documents behind Tabs 2B, C, and D all contain communications protected by the attorney-client privilege or work product doctrine. These documents are being submitted to the Court because they are covered by entries on the schedule appended to defendants' special master motion. The balancing test applicable to deliberative documents, of course, does not apply here.

The document behind Tab 2B is part of a facsimile from a trial attorney with the Department of Justice's Civil Division that was sent to an OIG staff person (as evidenced by the fax line at the top of the page). The document contains attorney notes and comments regarding a proposed agreement involving First Data Bank and Medi-Span. Other, non-privileged, documents created by defense counsel that were included with the facsimile transmission were

[5] The fact that Carrier personnel provided comments on the draft notice does not vitiate the deliberative process privilege - the reasons for this are set forth more fully in the discussion relating to the document behind Tab 2E.

released to defendants on November 21, 2008. The bold-face comments in in the text, cross-outs, and marginalia were inserted by a DOJ attorney and constitute his work product. The document is also protected by the attorney-client privilege in light of its transmittal to agency staff.

The documents behind Tab 2C are from the Office of General Counsel (OGC) for DHHS. Other documents which were not created by attorneys that were part of the same package of material have been produced to defendants. The document bearing Bates HHC902-0648 is from an OGC Weekly Activity Report and is protected by the attorney-client privilege. Moreover, it is not relevant to any claim or defense in this case. The hand-written comments on the document bearing Bates HHC902-902-0651 were by an OGC attorney. It also is protected from release by the attorney client privilege.

The documents behind Tab 2D were written by an attorney in the OGC for HHS. It is clear from the face of the documents that they constitute an attorney-client communication and are privileged.

The document behind Tab 2E is a draft version of a Durable Medical Equipment Regional Carrier (DMERC) medical policy. The document is wholly irrelevant to any claim or defense in this case – and is also privileged. The document is almost exclusively concerned with coverage issues. The term "coverage" relates to whether and under what circumstances, Medicare or Medicaid will pay for an item, supply, or service. For example, the question of whether the provision of a particular item or service was medically necessary in light of a patient's condition is, essentially, a coverage issue. The document also briefly addresses coding - that is, the issue of which alpha-numeric codes should be used on a CMS claim form. Although

the document relates to nebulizers and inhalation drugs, the cost of, or Medicare payment amount for, these drugs is simply not a subject covered in any way by the document.

From the fax line at the top of the page, it appears that the draft policy was sent to the Medical Director at a Durable Medical Equipment Regional Carrier (Robert Zone, MD). DMERCs are contractors used by Medicare to administer payment of claims to Medicare. The fact that the document was shared with a DMERC medical director does not vitiate the protection afforded by the deliberative process privilege. The case law relating to the deliberative process privilege recognizes that the sharing information with, and seeking input from, consultants is consistent with an agency's deliberative function when the agency solicited the information as part of its deliberative process. *See Dow Jones & Co. v. United States Dep't of Justice*, 917 F.2d 571, 575 (D.C. Cir. 1990); *Ryan v. United States Dep't of Justice*, 617 F.2d 781, 789-90 & n.30 (D.C. Cir. 1980) (responses from member of Congress to agency questionnaires held privileged); *Hoover v. United States Dep't of the Interior*, 611 F.2d 1132 (5th Cir. 1980); *Lead Indus. Ass'n v. OSHA*, 610 F.2d 70 (2d Cir. 1979); *Soucie v. David*, 448 F.2d 1067, 1078 n.44 (D.C. Cir. 1971); *Sakamoto v. EPA*, No. C 05-4019 SI, 2006 WL 2067848 (N.D. Cal. July 24, 2006), at *4-5.

Carriers are integral to the administration of the Medicare program. As evidenced by the draft document behind Tab 2E, at least one DMERC medical director was involved in the development of medical policy relating to the coverage of equipment and supplies used to administer inhalation therapy. This consultation was entirely consistent with the rationale behind the deliberative process privilege. CMS has as much interest in receiving candid input about draft policies from its carrier personnel as it does from those agency staff who are on the

Government payroll. In any event, in addition to being privileged, the document is completely irrelevant to any issue in this case.

B. Material From OIG Files or Relating to OIG Reports

1. Memoranda Relating to Draft OIG Reports and CMS Responses Thereto

The material behind Tab 3 is from the files of the OIG and consists of memoranda which record comments by agency personnel during entrance and exit conferences and memoranda recording discussion points raised at internal review team meetings. The 38 memoranda in this category relate to inspections or audits by OIG in connection with CMS programs and were created prior to issuance of the final OIG reports and the final agency responses to recommendations in the reports. The Government submits that rather than focusing its review on individual documents, the Court may instead determine that it would be more efficient to make a single determination regarding the entire class of material.

The Court's evaluation of this category of material should take into account the information which has been publicly available relating to the OIG inspections and audits, as well as the files which the Government has produced in these cases. The final OIG reports and agency comments are publicly released as soon as they are in final form. Additionally, the Government has produced the work paper files maintained by OIG relating to the reports. Accordingly, the Government has provided defendants with material which includes the information assembled during the audits and inspections, including all the pricing data, notes of contact with Government personnel (except when such contact was with CMS staff in the context of an entrance or exit conference), research performed by audit and inspection personnel, and anything else assembled during an audit or inspection.

The Court has already indicated that the Government need not produce, nor even submit *in camera*, draft versions of OIG reports. The entrance and exit conference notes and review team meeting notes are conceptually very similar to draft versions of the final written report. As with the draft versions of the reports, the conferences attended by OIG and other agency personnel relate principally to audit or inspection design, the content and format of the reports, and substance of the recommendations that are typically included in the reports. The declaration by Assistant Inspector General Brian Ritchie (*see* ¶¶ 9-13) sets out, in detail, the OIG's interest in protecting the information exchanged by agency personnel during these conferrals. Significantly, the audit and inspection findings are all publicly available. Accordingly, much of the information, including all the factual information assembled by the OIG is available from another source - a key criterion when evaluating a privilege claim.

Moreover, the privileged nature of precisely the type of material here at issue has been recognized in case law that is squarely on point. The decision in *Moye, O'Brien, O'Rourke, Hogan, & Pickert v. Nat'l R.R. Passenger Corp.*, 376 F.3d 1270, upheld the deliberative process privilege for internal work papers related to financial and performance audits by Amtrak's Office of Inspector General. The court of appeals held that OIG's audit work papers and internal memoranda "were both 'predecisional' and ''deliberative,' as required for material to fall within the 'deliberative process privilege'." *Id.* at 1279. The decision covered a much broader class of material than that now before this Court, and concluded that "the entire body of collaborative work performed by Amtrak's auditors, including advisory opinions, recommendations, and deliberations comprising part of process by which Amtrak's auditing policies were formulated, documented and contained comments and notes authored by all levels of auditors working on

[project at issue]" were protected by disclosure. *Id.* With respect to work by DHHS-OIG, the Government's privilege assertion is considerably narrower than that asserted by Amtrak. Here, the Government has released the bulk of the OIG's work papers, which include the data obtained during inspections and audits, background research, records reflecting contacts with third parties and other government officials (except in instances where the contact was with CMS personnel during an entrance or exit conference).

2. Draft OIG Reports

The material behind Tab 4 consists of draft versions of OIG reports or draft language that was being considered for inclusion in OIG reports. There are 11 documents in this category. The Court has already indicated that the Government shall not be required to release this type of material. The documents are being submitted only because they are covered by entries on the schedule submitted to the Court by defendants.

3. Other Documents from OIG Files

The material behind Tab 5 are draft versions of correspondence. The documents behind Tabs 5A through 5E are drafts that were created in 2005. During the November 13 status conference, the Court stated that material from after 2003 need not be produced. This material is being submitted to the Court only because it is covered by entries on defendants' schedule 1. The document at Tab 5F lays out draft language that was being considered for inclusion in a response to an inquiry from an United States senator. Again, the text of a *draft* letter is irrelevant.

The document at Tab 6A is a copy of an email from a DOJ attorney to an OIG staff person. The subject matter is generally the same as that covered by the attorney-client and

attorney work product documents at Tab 2B. Because the document is protected by privilege and doctrine, the Court should not order its release.

The document at Tab 6B is a letter to OIG's Office of Criminal Investigations regarding investigative work by Medicare's Region C DMERC. The document does not discuss drug pricing. The document is wholly concerned with "utilization" – that is, the review of claims data to assess whether the utilization of certain procedure codes in a certain area or by certain suppliers or providers may indicate that some portion of the services or supplies were not medically necessary. The Court should not order the Government to produce the document because it, one, is irrelevant to any claim or defense in this case and, two, details agency investigative work and is protected from disclosure by the Government Investigative Files privilege. *See Black v. Sheraton Corp. of America,* 564 F.2d 531, 541 (D.C. Cir. 1977).

Conclusion

Abbott has no need for any of the documents submitted *in camera* to the Court. The documents are irrelevant to any issue which is truly implicated in this case. The Court has already resolved the key issue of interest to Abbott by virtue of its November 2006 Order in which it construed the term AWP pursuant to its plain language. Moreover, even if there was an open issue regarding Governmental intent and this pricing term, it would be resolved by reference to public policy pronouncements by CMS. The only documents from CMS which could possibly be relevant to defendants' scienter are those which were publicly available during the claims periods in the cases brought by the United States. Finally, given that the documents are irrelevant, the potential chilling effect that the release of such documents would have on agency officials and the accomplishment of CMS's mission plainly outweighs defendants' interest in

their disclosure. "Moreover, in addition to the chilling effect that disclosure could have on agency employees, the release of incomplete, inaccurate or unsubstantiated information in [internal agency documents] could cause harm by providing the public with erroneous information...." *American Fed. of Govt. Employees.* 63 F.Supp. 2d 104, 108 (D. Mass. 1999) (citing *Providence Journal Co. v. United States Dep't of the Army*, 981 F.2d 552, 559 (1st Cir. 1992)). Finally, none of the documents evidence the Government's approval of the payment of mega spreads for pharmaceutical products.

Based on the foregoing, the United States respectfully requests that the Court not require the United States to produce to defendants the documents submitted *in camera* concurrently with this memorandum.

For the United States of America,

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Dated: December 8, 2008.

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "MEMORANDUM BY THE UNITED STATES RELATING TO THE IN CAMERA SUBMISSION OF DOCUMENTS FOLLOWING THE HEARING ON NOVEMBER 13, 2008 to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott
Justin Draycott

Dated: December 8, 2008